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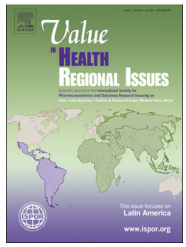

PATIENT-REPORTED OUTCOMES (PRO)

Evaluation of the Stroke-Specific Quality-of-Life (SSQOL) Scale in Mexico: A Preliminary Approach

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ABSTRACT

Objectives: The prevalence of stroke survivors with incomplete recovery in society has been estimated at 460/100,000 people, and one third of them require help in at least one daily activity. Two thirds of all deaths related to stroke in the world occur in low- and middle-income countries. The objective of the present work was to assess the reliability and validity of the previously translated Spanish Stroke-Specific Quality-of-Life (SSQOL) version 2.0 scales in Mexican stroke survivors. **Methods:** An observational and cross-sectional pilot study was conducted. Thirty-one patients who suffered stroke up to 1 year prior to the present study were included. Patients were interviewed twice in a 7-day period; other indexes and scales were applied. The reliability was assessed by using Cronbach's alpha (internal consistency) and test-retest by using Spearman's rho scores; the acceptability was evaluated by the floor and ceiling effects. **Results:** Ceiling and floor effects were observed for fewer than 20% of the patients. The overall internal consistency of the questionnaire was greater than 0.7 (Cronbach's α), with only two domains (family roles and personality) having lower internal consistency values. The results displayed high test-retest reliability: all domains had Spearman's rho scores of over 0.8. The questionnaire has adequate construct validity. **Conclusions:** Our preliminary results showed that the psychometric properties (acceptability and reliability) of the Spanish SSQOL questionnaire are good, encouraging, and comparable to those of other similar studies. This study is the first approach to validate the Spanish version of the SSQOL questionnaire in Mexican stroke survivors.

Keywords: Mexico, stroke-specific quality-of-life, questionnaire, stroke, validation.

Introduction

Stroke is the leading cause of disability and death in the world [1]. Each year, 15 million people worldwide suffer strokes. Of these, 5 million die and 5 million survive with disabilities, becoming a burden for their families and communities [2]. Two thirds of all deaths related to stroke in the world occur in low- and middle-income countries [1].

The risk of death due to stroke in Argentina, Chile, and Uruguay is double that in the United States and Europe [1–4]. Hispanics are the largest minority population in the United States, and Mexican Americans are the largest subgroup of Hispanics [5]. It has been documented that Mexican Americans experience a substantially greater incidence of ischemic stroke and intracerebral hemorrhage than do non-Hispanic white people, even though social and biological risk factors associated with stroke are similar between Mexican Americans and non-Hispanic white people [6]. Mexicans living in the United States have a high prevalence of diabetes mellitus, low socioeconomic status, and limited access to quality health care [6].

Ischemic heart disease and stroke are two of the main public health problems in Mexico [7]. According to data from the Health Ministry of Mexico, 5.6% of general mortality is due to stroke, with a rate of 25.6/100,000 inhabitants per year. This represents over 25,000 deaths from 2000 to 2004 [8]. It has been demonstrated that stroke is more prevalent in Mexico in people older than 55 years. Hypertension, diabetes mellitus, and excessive alcohol ingestion are the main risk factors for the recurrence of stroke, contributing to 70.1%, 38.9%, and 16.1% of cases, respectively [9].

In recent years, continuing advances in medical interventions have increased the survival rate of patients who suffer strokes. Therefore, the number of patients living with chronic degenerative diseases due to strokes, as well as the prevalence of disabilities among this population, has increased. Hence, significant interest has arisen in health-related quality of life (HRQOL) as a tool to assess changes in patient health throughout the length of a patient's life [10,11]. Patients usually lose functionality after

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suffering strokes, and social, emotional, physical, and occupational impairments arise. The measurement of HRQOL is crucial to obtain a complete understanding of the actual status of the patient after a health care intervention. There are conventional clinical scales that measure the functionality of poststroke patients, but these do not evaluate limitations in work reintegration, emotional adjustment, or capacity for leisure or recreation [12].

Various specific instruments for assessing poststroke HRQOL offer the advantage of assessing domains relevant to stroke, such as vision or language. These, however, are not available in all languages, and some are proxy versions (addressed to the primary caregiver) [3]. Among these tools is the Stroke-Specific Quality-of-Life (SSQOL) scale, which was developed as a comprehensive measure of multiple effects in poststroke patients. The scale consists of 49 questions grouped into 12 domains [13]. The SSQOL questionnaire has been translated into Danish and German, but only the Danish version has been appropriately validated [14–16]. The SSQOL questionnaire is an appropriate tool to measure the HRQOL of poststroke patients.

Because Mexican Americans have a high risk of stroke, evaluation of the reliability and validity of the SSQOL questionnaire in Mexican stroke survivors is an important health objective for both nations.

The objective of the present work was to assess the reliability and validity of the previously translated Spanish SSQOL version 2.0 scales in Mexican stroke survivors.

Methods

This was an observational, longitudinal, cross-sectional validation study in patients who had a stroke and were treated with dapsone during the acute phase of their stroke. The present study was performed at the National Institute of Neurology and Neurosurgery (NINN) in Mexico City. The recruitment period was from June until September of 2010. The cross-cultural adaptation of the SSQOL questionnaire into Spanish was done by Linda S. Williams and colleagues. They used the translation and back translation methods. The Spanish version of the SSQOL questionnaire was reviewed by medical staff at the NINN and by poststroke patients [13].

The SSQOL questionnaire consists of 49 questions grouped into 12 domains [13]; each individual domain consists of 3 to 10 items that are averaged to generate an overall score, with a minimum value of 1 (meaning the worst outcome) and a maximum value of 5 (meaning the best outcome). Any translated questionnaire test method needs to be assessed for validity and reliability as if it were a new instrument. The validity and reliability of the Spanish version of the SSQOL questionnaire in Mexican subjects were assessed by using different statistical tests further described in the "Data Analysis" section [15].

Subjects and Data Collection Procedures

Thirty-one ambulatory poststroke patients who had received treatment at the NINN in Mexico City were included in this study. The recruitment period was from June until September of 2010.

We included patients of both genders, who were older than 18 years and who had been diagnosed with a stroke up to 1 year prior to the present study and were willing to be visited at home. Exclusion criteria were inability to speak, dementia, verified psychiatric disorders, failure to complete the questionnaire and/or to understand its contents, and an elapsed time of over 1 year since stroke diagnosis. Elimination criteria were death of the patient and an inability to locate the patient during the study period.

All participants provided informed consent to participate in the study, in accordance with Mexican laws [17]. Ethical approval was obtained from the NINN Review Board before study initiation. Patient data, such as sociodemographic characteristics (age, gender, and employment status), stroke type, and vascular risk factors, were collected at the hospital from patient medical records. Patients were interviewed considering a minimum of 6 months after the stroke was diagnosed. During the patient interview, the Spanish version of the SSQOL questionnaire and conventional functionality scales including the Barthel index (IB), short-form 36 health survey (SF-36), Beck's Depression Index (EDB), and the National Institutes of Health Stroke Scale (NIHSS) were applied to assess convergent validity. We performed retests by providing copies of the SSQOL questionnaire to each patient and instructed patients to complete and return the questionnaires 1 week later [13,18–21]. All tools used in this study were in Spanish, and all measurements were rendered under the supervision of the study's primary investigator.

Data Analysis

The following statistical tests were used to validate the Spanish version of the SSQOL questionnaire:

The acceptability of the questionnaire was assessed by determining the ceiling and floor effects. Acceptable ceiling and floor effects are those under 20% [22].

Internal consistency and reliability were assessed by Cronbach's alpha tests. Cronbach's alpha values above 0.70 were considered acceptable [23,24].

The stability of the questionnaire was evaluated by measuring its test-retest reliability. The correlation between the test and the retest was assessed by Spearman's rho (r_s). An r_s value of above 0.80 was considered to be a satisfactory level of stability. A Wilcoxon test for dependent groups was also performed to reinforce the assessment [15].

The construct validity was assessed by comparing the linear association scores on specific domains of the SSQOL questionnaire with results from the SF-36, EDB, NIHSS, and IB scales via Spearman's rho tests. An r_s score between 0.30 and 0.60 indicated moderate association, and an r_s score greater than 0.60 denoted a strong association. The correlation coefficient (r^2) was also assessed; a score close to 0.5 on this measure was considered acceptable [15].

Convergent and discriminant validity were assessed by using the Pearson's correlation (r_p) for each item in relation to its domain. Convergent validity (as opposed to discriminant validity) was considered to be present when the item was moderately correlated with its domain ($r_p \geq 0.40$) [15,25].

All the before-mentioned thresholds hereby used are acceptable in the literature for validation [15,22–25].

The aforementioned statistical analyses were performed by using the SPSS version 13 statistical software package.

Results

Participants

Thirty-one patients who had suffered a stroke were included in the pilot study. Table 1 shows the sociodemographic characteristics of the participants. The average age of the population was 57.42 years (range 19–86 years). The number of male and female participants was similar. Most were married, and 54.8% had not completed basic education (junior high school). The main subtypes of stroke suffered by participants were atherothrombotic (38.7%) and cardioembolic (29.0%). The main concomitant diseases among these patients were hypertension (five patients,

Table 1 – Sociodemographic characteristics of patients.

Variable	n (%)
Average age, y (range)	57.42 (19–86)
Female	15 (48.4)
Male	16 (51.5)
Marital status	
Single	4 (12.9)
Married	23 (74.2)
Widowed	1 (3.2)
Free union	3 (9.7)
Schooling	
Illiterate	1 (3.2)
Elementary	13 (41.9)
Junior high incomplete	3 (9.7)
Junior high complete	6 (19.4)
High school incomplete	1 (3.2)
High school complete	2 (6.5)
Baccalaureate	5 (16.1)
Stroke subtype	
Atherothrombotic	12 (38.7)
Cardioembolic	9 (29.0)
Lacunar	2 (6.5)
Undetermined origin	8 (25.8)
Concomitant illness	
DM	1 (3.2)
HTN	5 (16.1)
Cardiopathy	3 (9.7)
DM + HTN + cardiopathy	1 (3.2)
DM + HTN	5 (16.1)
HTN + cardiopathy	1 (3.2)
None	7 (22.6)
Dietary and hygiene habits	
Alcohol ingestion	3 (9.7)
Tobacco	1 (3.2)
Tobacco + alcohol ingestion	11 (35.5)
WS	1 (3.2)
HTN + alcohol ingestion + tobacco	3 (9.7)
None pertinent	12 (38.7)

DM-2, diabetes mellitus type 2; HTN, hypertension; WS, exposure to wood smoke.

16.1%) and hypertension plus diabetes mellitus type 2 (five patients, 16.1%). Tobacco use plus alcohol ingestion was reported by approximately one third of the participants.

Quality of Life

Participants' average scores on the quality-of-life (scale ranges from 1, indicating "poor," to 5, indicating "excellent"), EDB (ranges from 1, indicating "normal condition," to more than 40, indicating "extreme depression"), IB (ranges from 0 to 100; lower scores indicating increased disabilities), NIHSS (ranges from 0, indicating "normal condition," to 42, indicating "coma condition"), and SF-36 (ranges from 0, indicating "the worst health state," to 100, indicating "the best health state") scales were 3.68, 12.65, 87.58, 0 to 17, and 59.84 points, respectively. The mental health's domain of the SF-36 scale data ranged from 20 to 100, with an average of 63.32.

Table 2 presents the average values for each domain of the Spanish version of the SSQOL questionnaire. Two domains stand out: subjects scored an average of 4.08 on the self-care domain, but they averaged only 2.95 on the social roles domain.

Statistical tests results are also presented in Table 2. Acceptability results showed that fewer than 15% of the respondents chose the minimum possible score of 1 in each domain. However, fewer than 40% chose the highest possible score of 5. The domain that presented the highest floor effect was work and productivity (12.9%), while the self-care domain had the highest ceiling effect (38.7%), followed by upper-extremity function and vision, with 29% and 25.8%, respectively. Internal consistency scores for items within each domain were satisfactory, with Cronbach's alpha scores ranging between 0.81 and 0.96. On the domain level, Cronbach's alpha scores were unsatisfactory only for the family roles (0.57) and personality (0.69) domains. Spearman's rho values calculated on our test-retest assessment reflected acceptable stability. The other 10 domains achieved Spearman's coefficients (r_s) of greater than 0.8 (Table 2). The mood domain showed a significant correlation (0.87), while the vision and thinking domains did not show a significant correlation (r_s scores of 0.71 and 0.79, respectively).

Table 3 presents the construct validity of the Spanish SSQOL questionnaire's domains against the IB, EDB, NIHSS, and SF-36 scales. The SSQOL questionnaire's mobility domain was found to have an association with the physical function domain of the SF-36 scale ($r_s = 0.801$), while the SSQOL questionnaire's energy domain had a weak association with the SF-36's vitality domain ($r_s = 0.28$). The mood, vision, language, thinking, and personality domains were found to have an association with the same domains of the EDB and NIHSS scales ($r_s = -0.642$, -0.544, -0.601, -0.511, and -0.444, respectively). The r_s negative values are because the SSQOL scale has a different ranking interpretation, with higher values meaning better quality of life, whereas in the EDB and NIHSS, this is the opposite (lower values mean better health).

Table 3 also shows that 9 out of 12 domains of the Spanish SSQOL questionnaire had r^2 values below 0.50; the energy domain had an r^2 value of only 0.08.

The convergent validity of each SSQOL questionnaire item within the domain in which it was included was high, with values of r_p ranging from 0.800 to 0.990. However, when each item was compared with a different domain, r_p values ranged between 0.037 and 0.350, thereby indicating discriminant validity.

Discussion

The results of the study showed that the psychometric properties of the Spanish version of the SSQOL questionnaire are appropriate. The study showed that the questionnaire has adequate internal consistency and validity.

Evaluation of the acceptability of the questionnaire to Mexican patients showed that all domains were below the threshold reported for floor effects (20%). However, while the work and productivity domain had a floor effect score below the threshold (12.9%), this score is above those reported by Williams et al. [13] and Muus et al. [15], the authors of the English and Danish versions of the SSQOL questionnaire, who reported floor effect scores of 3.0% and 0.7%, respectively. In this study, the marginal floor effect might be explained by the timing of questionnaire implementation: questionnaires were completed an average of 6 months poststroke in this study, whereas Muss et al. tested subjects an average of 3 years after the stroke event [15]. This may indicate that the participants in the present study did not have adequate recovery time before rejoining the workforce.

In contrast, Williams et al. [13] applied the questionnaire to patients an average of 3 months after the stroke, and the patients had lower floor effect scores in the work and productivity domain than did the patients in our study. Therefore, the time elapsed between the stroke events and the questionnaire, by itself, is not sufficient to explain the differences in floor effect in the work and

Table 2 – Reliability of the SSQOL-Spanish Version Questionnaire, internal consistency, floor and ceiling effect, and stability.

SSQOL Domain	Number of items	Mean score ± SD	Floor and ceiling effects (%)	Internal consistency, Cronbach's α	Test-retest reliability	
					Spearman's ρ	P
Mobility	6	3.85 ± 1.15	3.2, 12.9	0.96	0.96	0.512
Energy	3	3.48 ± 1.16	6.5, 16.1	0.90	0.92	0.217
Upper-extremity function	5	3.93 ± 1.13	3.2, 29	0.92	0.92	0.632
Work and productivity	3	3.54 ± 1.30	12.9, 9.7	0.94	0.80	0.053
Mood	5	3.89 ± 0.95	3.2, 16.1	0.85	0.87	0.008
Self-care	5	4.08 ± 1.24	3.2, 38.7	0.97	0.94	0.632
Social roles	5	2.95 ± 0.99	3.2, 6.5	0.81	0.93	0.549
Family roles	3	3.73 ± 0.96	3.2, 12.9	0.57	0.83	0.095
Vision	3	4.02 ± 0.92	3.2, 25.8	0.82	0.71	0.267
Language	5	3.69 ± 0.99	3.2, 16.1	0.94	0.92	0.490
Thinking	3	3.68 ± 1.11	3.2, 16.1	0.90	0.79	0.293
Personality	3	3.30 ± 1.04	6.5, 6.5	0.69	0.90	0.656

Note: Out of the 31 patients, 30 were evaluated for test-retest validity, as 1 patient failed to complete the retest after having completed the first series of questionnaires.
SSQOL, Stroke-Specific Quality-of-Life.

productivity domains. Most of the recruited patients in the present study had low incomes and did not have rehabilitation therapy, probably due to lack of income to attend to private facilities and/or to pay out-of-pocket transportation to attend to NINN; these facts might have affected the results of the investigation. Rehabilitation therapy facilitates work reincorporation among stroke survivors; therefore, the quality of care in health care institutions and the socioeconomic conditions of patients are two important factors to consider when explaining the poor employment outcomes of our sample. Major difficulties regarding work reintegration have been reported in other studies in which reintegration of poststroke patients into their daily life activities was difficult [26–28].

Evaluation of the questionnaire's acceptability with respect to the ceiling effect (the proportion of patients who are inclined to respond with the highest score) revealed that self-care, upper-extremity function, and vision domains were above the threshold for displaying a ceiling effect (20%). This is similar to the results obtained with the Danish and English versions of the questionnaire. The time elapsed between the stroke event and the administration of the SSQOL questionnaire may contribute to these findings; had poststroke patients taken the questionnaire 1 month after the stroke event, they might not have achieved adequate physical recovery by that time [13,15].

In the Spanish version of the SSQOL questionnaire taken by Mexican patients, most domains exceeded Cronbach's alpha score of 0.8, thereby revealing that items within each domain measure the same concept [29]. However, the family roles and personality domains had Cronbach's alpha scores of below 0.6, lower than those obtained by Williams et al. [13] (0.79 and 0.77, respectively) and Muus et al. [15] (0.81 and 0.89, respectively). The sample size of the cited validation studies was 72 and 152 patients, respectively, larger than that of the present study, which was single-center. These issues indicate that Cronbach's alpha scores might depend on the sample size as it is discussed in the Muus et al. [15] work.

Test-retest stability was satisfactory; patients displayed correlations between 0.71 and 0.96 on SSQOL questionnaire domains between the first test and the second test, which was taken 1 week after the first (Table 2). For the American version of the SSQOL questionnaire, the correlation between an initial

Table 3 – Construct validity results of the SSQOL-Spanish Version Questionnaire domains.

SSQOL Domain	Comparison scale	Spearman's ρ	r^2	P
Mobility	SF-36, physical function subscale	0.801	0.64	<0.01
Energy	SF-36, vitality subscale	0.28	0.08	0.13
Upper-extremity function	NIHSS, upper limb subscale; Barthel Index	0.765	0.59	<0.01
Work and productivity	SF-36 physical role limitations	0.613	0.38	<0.01
Mood	Beck's Depression Index	−0.642	0.41	<0.01
Self-care	Barthel Index	0.787	0.62	<0.01
Social roles	SF-36, social functioning subscale	0.442	0.20	<0.01
Family roles	SF-36 emotional and physical role limitations	0.636	0.40	<0.01
Vision	NIHSS visual field and ocular movement scores	−0.544	0.30	<0.01
Language	NIHSS scale, dysarthria and aphasia subscales	−0.601	0.36	<0.01
Thinking	NIHSS scale, orientation and commands scores	−0.511	0.260	<0.01
Personality	Beck's Depression Index	−0.444	0.20	<0.05

NIHSS, National Institutes of Health Stroke Scale; SF-36, short-form 36 health survey; SSQOL, Stroke-Specific Quality-of-Life.

evaluation and a reevaluation 2 hours later was 0.92 [18]. The Danish version reported test-retest correlations between 0.65 and 0.99, with an assessment interval of 1 to 2 weeks [19]. Meanwhile, patients who took the German version of the SSQOL questionnaire had test-retest correlations of 0.69, with an assessment interval of 1 year [22]. The results showed that a shorter test-retest interval increased the test-retest correlation and yielded optimal results ($r_s \geq 0.8$), thereby indicating good stability. During this study, mood domain scores were highly correlated between the first and second tests.

Construct validity scores (r^2) on the SSQOL questionnaire ranged between 0.08 and 0.64 (Table 3). These results show adequately linear relationships between most SSQOL questionnaire domains and their respective comparison scales (IB, EDB, SF-36, and NIHSS). These results are similar to those reported by Williams et al. [13] and Muus et al. [15]. The energy domain of the SSQOL questionnaire, however, had a less linear relationship with the vitality subscale of SF-36 ($r^2 = 0.08$) than that found by Williams et al. [13] and Muus et al. [15] ($r^2 = 0.5$). This indicates that the energy domain is described more distinctly by the generic scale (SF-36) than by the specific SSQOL scale in the present sample.

Our findings show a moderate correlation between the social roles domain and the overall results of the SF-36 questionnaire ($r^2 = 0.20$); this correlation was smaller than that observed by Muus. et al. [15] at 3 years poststroke ($r^2 = 0.40$) and larger than that reported by Williams et al. [13] at 3 months poststroke ($r^2 = 0.01$). This difference may be explained by the elapsed time between the stroke event and the administration of the questionnaire: the process of social adaptation (the longer the recovery time, the better the adaptation) tends to counteract perceived differences in QOL. This fact could also be explained in a similar manner by means of a generic measure (SF-36) and a specific measure (the SSQOL questionnaire) [15].

For the mobility domain, the correlation between the SSQOL questionnaire and SF-36 was an r^2 value of 0.64 in our sample. This correlation is similar to that found using the Danish version of the SSQOL questionnaire ($r^2 = 0.62$) but higher than that found using the American version ($r^2 = 0.41$). This suggests that the SSQOL questionnaire is capable of measuring patient mobility in a manner similar to the SF-36 questionnaire.

SSQOL questionnaire scores for the work and productivity domain had similar correlation strengths with the SF-36 questionnaire to those obtained in the original American and Danish versions; the r^2 scores were approximately 0.3 in all three cases. These scores indicate that the SSQOL scale describes important aspects of work and productivity not described by the SF-36 scale. In this study, the SSQOL questionnaire's language, thinking, and vision domains showed weak correlations with those in the NIHSS ($r^2 = 0.36$, 0.26, and 0.3, respectively); these results were similar to those found by Williams et al. [13] and Muus et al. [15]. This suggests that the SSQOL questionnaire has qualities that describe important aspects of the HRQOL that are not considered by the NIHSS scale.

The results of the language domain and its low correlation with the NIHSS scale are the consequences of not including patients with severe aphasia; the exclusion was done to reduce variability and to avoid the use of a proxy questionnaire version. The selection bias did not overestimate the language score value as it resulted in a moderate ceiling effect of 16.1%. To avoid and/or to minimize selection bias, it is necessary to use special SSQOL questionnaire versions such as the "Stroke and Aphasia Quality of Life Scale-39" that has been developed and validated to be applied to patients with severe aphasia or dysarthria [22].

In addition, the mood and personality domains of the SSQOL questionnaire were correlated with the EDB scale ($r^2 = 0.41$ and 0.20, respectively), similar to findings in the American version ($r^2 = 0.43$ and 0.33, respectively), thereby indicating that these domains provide adequate descriptions of emotional aspects in the SSQOL scale as opposed to the EDB scale.

The items within individual SSQOL questionnaire domains displayed the expected levels of convergent validity ($r_p \geq 0.40$). For example, in the language domain, the item related to speaking trouble had an r_p value of 0.944, indicating a strong correlation between the item and its respective domain (language), but the same item (speaking trouble) and other domain (vision) had an r_p value of 0.244, showing a very weak correlation between the item and other domain. This shows the importance of the items in their respective domains and the discriminant validity of the instrument.

There are several limitations to the present analysis. In all cases, it was necessary to explain each item to the patient and/or the patient's caregiver. This has the potential to introduce bias during the retest, which was self-administered by patients in an autonomous and independent manner. Furthermore, it must be noted that despite the fact that all participants knew how to read and write, they had different levels of education, thereby limiting the uniformity of this tool.

As mentioned above, this investigation is a pilot study of 31 patients. It is recommended that a larger patient sample be tested to assess the HRQOL with the Spanish version of the SSQOL questionnaire.

Conclusions

Our preliminary results showed that the psychometric properties (acceptability and reliability) of the Spanish SSQOL questionnaire are good, encouraging, and comparable to other similar studies. This study is the first approach to validate the Spanish version of the SSQOL questionnaire in Mexican stroke survivors.

A larger Spanish population is needed to draw definitive conclusions. QOL assessment in Spanish-speaking patients with stroke is greatly needed for those living in the United States and those living in their native countries.

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